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Martin A Smith

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EXAMINER

TUNG, JOYCE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1637

The response filed 11/23/10 to the Office action has been entered. Claims 1-15, 17-18, 20-35 and 66 are pending.

1. Regarding the rejection of claims 1-12, 14, 15, 17-18, 20-21, 23-35 and 66 under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US Patent No. 6,645,717, issued Nov. 11, 2003; previously cited) as evidenced by Burgoyne (U.S. Patent No. 5,496,562 A; cited in the IDS) and Mitchell (WO 00/21973; previously cited).

The response argues that the Office has ignored the language of the claims "subsequently" for connecting one step to another step in the claimed method. The Office action mailed 5/25/10 states that Mitchell et al. disclose that the order of steps can be reversed, leading to the same end result, i.e. nucleic acid from lysed cells immobilized onto a filter (see Mitchell et al. page 2, third paragraph), which cites the method comprising:

"According to the present invention, there is provided a method for isolating nucleic acid which comprises:

(a) applying a sample comprising cells containing nucleic acid to a filter, whereby the cells are retained as a retentate and contaminants are removed;

(b) lysing the retentate from step (a) whilst the retentate is retained by the filter to form a cell lysate containing the nucleic acid;

(c) filtering the cell lysate with the filter to retain the nucleic acid and remove remaining cell lysate;

(d) optionally washing the nucleic acid retained by the filter; and

Art Unit: 1637

(e) eluting the nucleic acid, wherein the filter composition and dimensions are selected so that the filter is capable of retaining the cells and the nucleic acid."

As also stated in MPEP 2144.04 IVC:

C. Changes in Sequence of Adding Ingredients

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Therefore it would have been prima facie obvious to one of ordinary skill in the art to reverse the order of steps in the method of Smith et al., since the end result is still the same.

The response argues that the filter of Smith can only contain a finite amount of the coating solution. However, this does not relate to a limitation in the claims.

The response further argues that Mitchell et al. teach away from the method of Smith and the present invention because the method of Mitchell avoids drying the filter which may cause nucleic acid shearing. However, Mitchell is relied upon in the rejection only with respect to the teachings that the order of the steps can be reversed.

The response argues that rejection does not apply to claims 23-24. However, as evidenced by Mitchell et al., binding of the nucleic acid to filters is generally non-ionic (page 9, third paragraph). Since known non-ionic interactions include the ones listed in claim 24, and due to the complexity of the system, at least one type of interaction listed in claim 24 inherently occurs within DNA immobilized onto a membrane. For example, as stated by Mitchell et al. (page 9, first paragraph):

Art Unit: 1637

"It is postulated that nucleic acid-nucleic acid interactions themselves are important in maintaining a sufficiently high cross-sectional area to retard movement of the nucleic acid through the filter".

Since DNA-DNA interactions include at least hydrogen bonding and dispersion forces, the claim limitations are anticipated.

The response argues that Smith et al. do not disclose concentrating cells in a solid phase medium. However, Smith et al. disclose depositing whole blood onto a filter (col. 10, lines 42-45). This is interpreted as concentrating cells in a solid phase medium.

Based upon the analysis above, the rejection is maintained.

2. Regarding the rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 6,645,717, issued Nov. 11, 2003; previously cited), as evidenced by Burgoyne (U.S. Patent No. 5,496,562 A; cited in the IDS) and Mitchell (WO 00/21973; previously cited), and evidenced by Whatman filter paper overview (downloaded from the internet on May 21, 2010):

The response argues that the "Whatman filter paper overview" is from the internet on May 21, 2010 and the reference is improperly cited because of the date. However, this is cited only as evidence for the size of the filter.

Based upon the analysis above, the rejection is maintained.

3. Regarding the rejection of claim 22 under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 6,645,717, issued Nov. 11, 2003; previously cited), as evidenced by Burgoyne (U.S. Patent No. 5,496,562 A; cited in the IDS) and Mitchell (WO 00/21973;

Art Unit: 1637

previously cited), and further in view of Qiagen Genomic DNA Handbook (pages 17-22, August 2001).

The response does not have a specific argument for this rejection. With the same reasons as set forth above, the rejection is maintained.

4. No claims are free of the prior art.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/

Primary Examiner, Art Unit 1637

/Joyce Tung/

Examiner, Art Unit 1637

December 14, 2010